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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,144	12/15/2003	Su Il Yum	DURE-050	6360

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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06/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,144	YUM ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10-50 and 52-79* is/are pending in the application.

4a) Of the above claim(s) *32-40,52,53,56 and 65-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,10-31,41-50,54,55,57-64 and 68-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/09 & 3/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of request for extension of time, Request for continued examination under 37 CFR 1.114, and amendment and remarks filed 3/27/09. The examiner further acknowledges receipt of IDS filed 3/27/09 and 5/18/09. Claim 56 is amended. No claim is canceled. Claims 1, 2, 4-8, 10-50 and 52-79 are pending. Claims 32-40, 52, 53 and 65-67 are withdrawn from consideration.

Claim 54: Applicant indicates in the remarks that claim 54 is amended. But, claim 54 is not currently amended.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/27/09 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 54 recites organic acid derivative and the boundaries of protection sought organic acid derivatives are not clear making the scope of the claim unclear and indefinite.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 4-8, 10-50 and 52-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al. (US 5,747,058).

Tipton discloses a composition comprising HVLCM, and with sucrose acetate isobutyrate specifically employed (abstracts, column 2, lines 43, 46, 55, 60-65; column 4, lines 2-67; column 5, lines 1-33; column 8, lines 51-67; column 12, lines 46-50) meeting the recitation of HVLCM in the claims; the composition contains surfactants (column 11, lines 40-67; column 12, lines 1-17) in amounts of 0.5-30% and having 1-5% preferred that meets network former of the claims and specifically claims 26-29, oily components (column 12, lines 18-45) in amounts of 0.5-50% and with 1-10 preferred meeting the rheology modifier of the claims and specifically claims 23-25, water or DMSO or ethyl lactate or triacetin (column 2, lines 49 and 50; column 12, line 51) meeting the solvent requirements of the claims, additives such as preservative, antioxidants, stabilizers, vitamins (column 12, line 65 to column 13 line 4) meeting claims 17 and 18, and drugs such as codeine (column 7, line 62) meeting claims 29, 30, 70, 71; the formulation of Tipton is placed in gelatin capsules for oral administration (claim 88) meeting claims 13 and 14. Claims 46-50, 75 recite the properties of the composition and the composition of Tipton would inherently possess these properties. The composition of Tipton would inherently possess the characteristics of the composition recited in claims 2 and 4.

Tipton describes compositions that contain CAB and HVLCM and solvents separately (see column 4). Regarding the amounts of HVLCM recited in claims 19-22, in the absence of factual evidence, the claimed amounts are not inventive over the prior art. Regarding the amounts of the drugs, it is noted that Tipton teaches percent amounts of drugs and the specific amounts recited in claims 41-45 is not inventive over the percent amounts taught by Tipton in the absence of factual showing of unexpected results. Furthermore, regarding claims 25 and 16, it is noted that the composition of Tipton is encapsulated and use of soft and hard gelatin capsules are

known in the art so that it would be obvious to place the formulation in soft or hard gelatin capsule for delivery. Tipton clearly teaches that the composition contains **additives** that modifies the properties of the composition as desired (column 3, lines 31-44); the additives are A) biodegradable polymers and combinations and one or more of these bodegradable polymers can be use (column 9, lines 8-27), B) Non-biodegradable polymers, with CAB and CAP preferred (column 9, lines 28-41), C) oils and fats (column 9, lines 42-60), D) carbohydrates and carbohydrate derivatives (column 9, lines 61-67). The composition of Tipton contains HVLCM, drugs and solvent and when SAIB is the HVLCM, the solvent is ethyl lactate, EL, ethyl acetate, benzyl alcohol, triacetin, N-methylpyrrolidone, propylene carbonate and glycofurol are preferred (column 10, lines 23-30) and these solvents are used in amounts of 5-55% (column 10, lines 31-37). One of the drugs in Tipton is codeine, which is an opioid. Tipton does not teach the oxycodone in claims 31, 63, 64 and 72. Since oxycodone and codeine are opioids, and specifically, oxycodone is derived from codeine, it is prima facie obvious that oxycodone can be used in place of codeine and expect to obtain similar relative potency.

Tipton does not exemplify one composition that has HVLCM, CAB, solvent, and rheology modifier. But Tipton teaches these HVLCM, drugs, solvent and additives are formulated and that the additives are added as desired to modify the properties. For example, oils are added to retard degradation and water uptake (column 9, lines 58-60) and isopropyl myristate, octyl palmitate, ethyl oleate, ethyl palmitate are preferred fatty acid esters (column 12, lines 34-40). Therefore, taking the teachings of Tipton, one having ordinary skill in the art at the time the invention was made would reasonably expect including additives such as polymers and oils would successfully modify the degradation and water uptake of the composition.

Response to Arguments

8. Applicant's arguments with respect to claims 1, 2, 4-6, 10-13, 17, 18, 23-30, 46-50, 54, 55, 57, 70, 71 and 76-78 have been considered as the arguments relate to the rejection under 35 USC 102, but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 3/27/09 have been fully considered but they are not persuasive.

10. Applicant argues the mouth wash composition cannot be put into a pill or capsule. The examiner agrees, but the mouthwash is an oral formulation and claims 1, 61,78 and 79 are not directed to capsule or pill so that it does not defy common sense that mouthwash composition is an oral composition. Furthermore, oral composition is an intended use and it does not defy common sense that it the mouth was composition can be used for the intended use, it would meet the composition. Also, Tipton specifically contemplates oral administration (column 3, lines 27; column 10, line 44).

11. The office does not propose modifying the mouthwash composition. Rather, claim 88 of Tipton says that the composition is placed within gelatin capsule for oral administration. If applicant has issues with claim 88 of Tipton, applicant may take appropriate steps to challenge the claim.

12. Most of applicant's arguments center around modification of the mouthwash of Tipton. However, as explained above, claim 88 places the composition in a capsule. Furthermore, the Tipton reference is not limited to the examples; and evaluation of the reference as a whole, including the claims would show that Tipton contemplates oral administration ad oral compositions.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618